UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,481	11/01/2001	Qun-Yong Zhou	P-UC 5016	4599

23601 7590 07/14/2003

CAMPBELL & FLORES LLP
4370 LA JOLLA VILLAGE DRIVE
7TH FLOOR
SAN DIEGO, CA 92122

EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	14

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/016,481	Applicant(s) ZHOU ET AL.	
	Examiner Dong Jiang	Art Unit 1646	

-- Th MAILING DATE of this communication appears on the cover sh et with th correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-90* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's preliminary amendment filed on 05 December 2002, and resubmitted in paper No. 13, filed on 12 May 2003 is acknowledged and entered. Following the amendment, the new claims 53-90 are added.

Currently, claims 1-90 are pending.

The following restriction requirement supercedes the one sent on 29 January 2003, paper number 10, because the previous restriction requirement was made based on claims 1-52, and there was no indication in the file that a preliminary amendment with the addition of the new claims 53-90 was filed at the time the first restriction requirement was made, although applicants indicate that the preliminary amendment was filed on December 5, 2002.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 and 17-26, drawn to an isolated prokineticin polypeptide, a variant or fragment thereof, and a pharmaceutical composition thereof, classified in class 530, subclass 300.

II. Claims 11 and 27, drawn to a method of stimulating GI smooth muscle with the polypeptide, classified in class 514, subclass 2.

III. Claims 12-15 and 28-31, drawn to a nucleic acid, a vector containing same, a host cell thereof, and a method of recombinantly producing the encoded polypeptide, classified in class 530, subclass 69.7.

IV. Claims 16 and 32, drawn to an antibody, classified in class 530, subclass 387.9.

V. Claims 33-36, 37 in part, and 38-46, drawn to a method of identifying a prokineticin receptor agonist, classification depending upon the chemical entity of the agonist.

VI. Claims 33-36, 37 in part, 38-41, and 47-52, drawn to a method of identifying a prokineticin receptor antagonist, classification depending upon the chemical entity of the antagonist.

VII. Claims 53-90, drawn to an isolated prokineticin receptor antagonist, a pharmaceutical composition thereof, a nucleic acid encoding the antagonist polypeptide, a vector containing same, a host cell thereof, and a method of preparing said polypeptide, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because:

Invention I is related to Invention II as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for the production of the antibody of Invention IV.

The polypeptide of Invention I is related to the nucleic acid of Invention III by virtue of encoding same. The nucleic acid molecule has utility for the recombinant production of the protein in a host cell. Although the nucleic acid molecule and the protein are related since the nucleic acid encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the nucleic acid may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The method of Invention III is related to the protein of Invention I as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the product as claimed may be isolated from their natural source or made by chemical peptide synthesis.

The polypeptide of Invention I is related to the antibody of Invention IV by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for

production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

Invention I is distinct from and unrelated to Inventions V and VI, wherein the polypeptide of Invention I can be neither made by nor used in the methods of Inventions V and VI, and wherein each does not require the other.

Invention I is distinct from and unrelated to invention VII because they are structurally and functionally distinct (antagonist) chemical entities.

Inventions II and III are distinct and unrelated, wherein the products of Invention III can be neither made by nor used in the method of Invention II, and wherein each does not require the other.

Invention II is distinct from and unrelated to Inventions IV and VII, wherein the antibody of Invention IV, or the polypeptide and the nucleic acid of Invention VII can be neither made by nor used in the methods of Invention II, and wherein each does not require the other.

Invention II is distinct from and unrelated to Inventions V and VI because Invention II has different process steps, different active agents, different starting and ending points, and is for a different purpose from those of Inventions V and VI, such that they require separate searches.

The nucleic acid of Invention III is distinct from and unrelated to the antibody of Invention IV because they are physically and functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other. The method of Invention III is distinct from and unrelated to the antibody of Invention IV because the antibody may be neither made by nor used in the method.

Invention III is distinct from and unrelated to Inventions V and VI, wherein the nucleic acid of Invention III can be neither made by nor used in the methods of Inventions V and VI, and wherein each does not require the other.

Invention III is distinct from and unrelated to invention VII because they are structurally and functionally distinct chemical entities.

Invention IV is distinct from and unrelated to Inventions V and VI, wherein the antibody of Invention IV can be neither made by nor used in the methods of Inventions V and VI, and wherein each does not require the other.

Invention IV is distinct from and unrelated to invention VII because they are structurally and functionally distinct chemical entities.

Invention V is distinct from Invention VI, wherein the method of Invention V is for identifying a receptor *agonist*, whereas the method of Invention VI is for identifying a receptor *antagonist*, thus they require different active compounds, and are for different purposes, such that requiring separate searches.

Invention VII is distinct from and unrelated to Inventions V and VI, wherein the products of Invention VII can be neither made by nor used in the methods of Inventions V and VI, and wherein each does not require the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

2. Furthermore, regardless of which Invention applicants elect above, further **restriction** is required under 35 U.S.C. 121:

A. Elect *one* specific amino acid sequence with SEQ ID NO from the following: SEQ ID NO:3, 6, 13 or 14 as they apply.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs is a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

In order to be fully responsive, Applicant must elect one from Groups I - VII, one from Group A, even though the requirement is traversed. Applicant is advised that neither

I - VII nor A and B are species election requirements; rather, each of I – VII, and A is a restriction requirement.

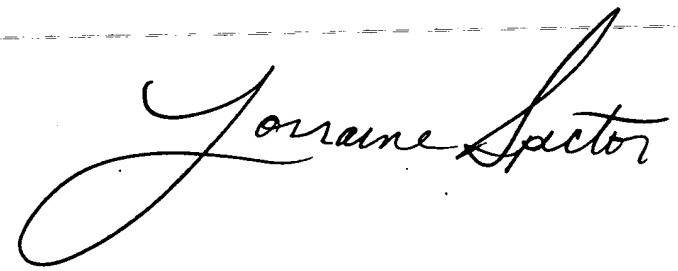
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



LORRAINE SPECTOR
PRIMARY EXAMINER

DJ
7/9/03